ANNOUNCEMENT OF DRAFT PROJECT REQUIREMENT

TITLE: MASTER CONTRACT FOR PRECLINICAL DEVELOPMENT

REFERENCE NUMBER: NIH-NIAID-DAIDS-03-18

Purpose of Announcement

The purpose of this announcement is two-fold: first, to inform potentially interested individuals, institutions and organizations of a draft project requirement of the National Institute of Allergy and Infectious Diseases (NIAID), National Institutes of Health (NIH), designed to establish a contract for the Development Resources Master Contract, and second, to solicit comments from interested parties with respect to the scope, design and requirements of this draft solicitation.

Please note that proposals are not being solicited at this time. With this announcement, the NIAID is soliciting comments and recommendations on draft Statement of Work in order to: (1) determine interest in this solicitation; (2) assure that requirements included in the documentation will meet the intent of the solicitation; and very importantly, (3) identify or clarify what may appear to be problems, conflicts, or obstacles for an institution or organization that might otherwise wish to become a potential offeror.

It is anticipated that one cost-reimbursement contract will be awarded for a period of five (5) years. As provided for by FAR.5.205 entitled “Special Situations,” a draft project requirement is being broadcast.

We encourage you to respond electronically to Brenda Brooks, NIAID Contracting Officer, on this matter, using the Response Guidelines provided below, to indicate issues or elements you are particularly in favor of, or which you find problematic to the response capacity of your institution or organization. Electronic responses should be submitted by Monday, April 15, 2002.

Please note that the Government does not intend to award a contract on the basis of this solicitation or to otherwise pay for the information solicited. Although “proposal” and “offeror” are used in this Announcement, your response will be treated as information only. It shall not be used as a proposal.

RESPONSE GUIDELINES

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Whether you review this draft project requirement as a potential future offeror or as a fact-finding exercise, the NIAID is interested in your feedback. The NIAID is actively soliciting input from academic and industry sources to improve and refine this draft requirement and is seeking to gauge the degree of interest in this effort. PROPOSALS ARE NOT BEING SOLICITED AT THIS TIME. Candid questions and concerns elicited by this notice are encouraged. Please note that the Government will not provide individual responses to questions/inquiries. However, the extent to which a dialogue may be established with any individual or business entity concerning a given issue raised by this notice shall, for purposes of fairness and compliance with Agency regulations, be determined by the NIAID Contracting Officer after consultation with the cognizant NIAID Technical Program Office.

Examples of feedback may include, but are not limited to:

1. Level of interest in pursuing a prime contract with the NIAID, or a subcontract, consultant or other collaborative relationship with a potential prime Contractor, for this requirement. If there is no interest at this time, please explain why.

2. Comments, questions and/or concerns regarding the scope and/or design of the Master Contract for Preclinical Development.

Responses should be clear and succinct. We do not desire the submission of any technical or cost proposals. Any critique of the draft project requirement should adequately describe concerns and offer recommendations and/or solutions, which might be used by the NIAID in refining the requirement. Critical technical concerns should be supported with questions posed in such a way as to point toward possible alternatives that may be pursued by the NIAID in refining some aspect(s) of the requirement.

Responses should be submitted electronically by **Monday, April 15, 2002**. All responses should include the name, position/title, telephone/extension, facsimile number(s), and electronic mail address(es) of the contact individual. The response should also identify the institution, organization, company, etc., and the complete street address (including, where applicable, location identifiers, e.g., office stop and room number) including zip code.

All response information should reference NIH-NIAID-DAIDS-03-18 and be directed in writing via electronic mail to:

Brenda Brooks, Contracting Officer
E-mail: bb76n@nih.gov
Phone: (301) 435-2765
Facsimile: (301) 402-0972 or (301) 480-5253

Additionally, please provide a copy to:

Jacqueline C. Holden, Senior Contracting Officer
E-mail: jh55b@nih.gov
Phone: (301) 496-7119
Facsimile: (301) 402-0972 or (301) 480-5253

DRAFT PROJECT REQUIREMENT

TITLE: MASTER CONTRACT FOR PRECLINICAL DEVELOPMENT

REFERENCE NUMBER: NIH-NIAID-DAIDS-03-18

I. INTRODUCTION

The development of vaccines to prevent the spread of HIV infection or counter bioterroism threats (BT) is among the NIAID's highest priorities. Likewise, there is a critical need to promote the development of novel microbicides for prevention of sexual transmission of HIV, particularly in the absence of an effective, or even partially effective, vaccine. While advances in immunology and molecular biology continue to offer an expanding array of approaches to the development of new candidate vaccines, the limited capacity to move promising concepts through the development process presents a barrier to the achievement of this goal. Limited industry involvement in developing both vaccines and microbicides requires the need for a nontraditional, proactive and developmentally oriented response by NIAID to meet this public health challenge. When promising candidates emerge from investigator-initiated research studies, there is a need to provide rapid support to quickly and efficiently move the candidates toward clinical lot production. The type of products needed to provide efficacy against HIV/AIDS or BT are currently not known, thus production facilities with the ability, flexibility and experience staff must be identified and readied for quick mobilization as promising new concepts are identified. Clinical testing of a product requires that the product first be approved for such testing by the Food and Drug Administration, and such approval is only achieved after considerable preclinical safety and immunogenicity testing. Since it is envisioned that many promising candidates will lack industry backing, there is a need to provide support for enabling studies leading to IND submission and approval. Providing sufficient support to move concepts with little or no industry support from the development stage through to production and FDA approval will greatly expand the pipeline of products reaching human clinical trial testing.

II. OBJECTIVE

The objective of this initiative is to expand the number of vaccine and microbicide products for HIV/AIDS, BT and other emerging diseases of national importance that can be evaluated in human clinical trial testing. This initiative will provide overall project management and the capabilities to support all phases of preclinical development, including process and product development, clinical lot production, formulation, preclinical enabling studies and associated tasks leading to the filing of investigational new drug (IND) applications. The Contractor will be required to assist in identifying products that are ready for development and production by assembling information on experimental vaccines and microbicides. This will be accomplished by collecting,

maintaining, analyzing and disseminating information arising from all preclinical development efforts, including data generated by SIV Vaccine Evaluation Units, the Integrated Preclinical/Clinical Program for HIV Topical Microbicides (IPCP/HTM), and other prevention grants and contracts. The Contractor will be required to identify potential subcontractors with the capability and interest in producing clinical product lots and to issue and administer subcontracts for the production of products as assigned by the Project Officer. The Contractor will also be required to perform all preclinical testing of the products necessary for Investigation New Drug (IND) application, either in-house or via subcontracts, and to compile and submit this data in the form of a formal IND submission to the FDA. The Contractor will be expected to provide information management and IND preparation and filing support as part of their in-house activities.

III. STATEMENT OF WORK

Specifically, the Contractor shall:

1. Provide overall project management to establish and meet development time lines, monitor progress, provide frequent verbal/written communication and updates to NIAID, ensure coordination among subcontractors, suppliers, NIAID and NIAID supported grantees or contractors, as well as ensure the most efficient and expeditious entry of a product into clinical trial.

2. Develop candidate vaccines as assigned by the Project Officer, including process development and production of GLP/GMP pilot lots suitable for phase I/II human trials, and perform the necessary characterization tests required for release for clinical use. Various types of vaccine concepts will be developed including but not limited to (a) synthetic peptides, (b) recombinant proteins, (c) plasmid DNA, (d) vector (bacterial or viral) based vaccines, (e) whole killed/virus-like particles, and (f) attenuated viruses.

3. Develop candidate non-vaccine prevention modalities as assigned by the Project Officer, including identification, characterization, process development and production, and formulation appropriate for human clinical trials. Various types of prevention modalities will be developed, including but not limited to (a) microbe direct inactivators, (b) inhibitors of attachment, fusion, or entry, (c) enhancers of natural mucosal defense mechanisms.

4. Carry out pre-clinical testing of vaccine and microbicide preparations as required prior to initial human clinical trial evaluation. This shall include testing candidate products for safety and in the case of vaccines, immunogenicity (both cellular and humoral) in small animals and, if appropriate non-human primates.

5. For each product produced and tested above and in collaboration with the vaccine or microbicide supplier, develop a Master File, Investigator's Brochure, and compile an Investigational New Drug Application (IND) including a vaccine or

microbicide trial protocol (provided by the Project Officer) appropriate for submission to the FDA for an IND.

6. Conduct market surveys and /or review scientific and industry publications on new or related vaccine and microbicide product development, create and utilize a database or databases identifying and comparing potential products, as well as preparation of reports of product characteristics that can be used to support selection and prioritization of candidates for further development.

7. Assist in identifying promising vaccine and microbicide candidates for development through compilation of data from animal studies. This will entail the development and utilization of a computer-based data management system to collect data generated in NIAID-supported animal studies, as directed by the Project Officer.